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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ENZO BIOCHEM, INC., et al.,	:	
Plaintiffs,	:	02-CV-8448 (RJS)
- against -	:	03-CV-3816 (RJS)
	:	03-CV-3817 (RJS)
AMERSHAM PLC, et al.,	:	03-CV-3819 (RJS)
	:	03-CV-8907 (RJS)
Defendants,	:	04-CV-1555 (RJS)
	:	04-CV-4046 (RJS)
AND RELATED CASES NAMING	:	
MOLECULAR PROBES, INC., et al., PERKINELMER, INC., et al., ORCHID BIOSCIENCES, INC., et al., AFFYMETRIX, INC., ROCHE DIAGNOSTICS GMBH, et al., AS DEFENDANTS AND/OR DECLARATORY JUDGMENT PLAINTIFFS.	:	

ENZO'S MEMORANDUM IN OPPOSITION TO
DEFENDANTS' RENEWED JOINT MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively, "Enzo") hereby oppose Defendants'[1] renewed joint motion for partial summary judgment ("the Renewed Motion") of: (1) no infringement, either literally or under the doctrine of equivalents of three of the eight (3 of 8) patents-in-suit, namely U.S. Patent Nos. 5,328,824 ("the '824 patent"), 5,449,767 ("the '767 patent"), and 4,994,373 ("the '373 patent") by some, but not all, of the accused products; and (2) no infringement of three (3) other patents-in-suit because two of the Defendants were allegedly "authorized" by Enzo to manufacture, use and sell certain accused products under relevant distribution agreements.

In making the instant motion, through which Defendants purportedly seek relief only on patent-related issues,[2] Defendants attempt to conceal from the Court critical facts and pre-litigation admissions made by Defendants -- including prior admissions that the patents-in-suit are valid and infringed by the very same accused products which they today contend do not infringe. Indeed, many of the Defendants actually marked the accused products with Enzo's patent numbers, thus putting the public on notice of their belief that the products were covered by Enzo's patent claims, and precluding them from subsequently contesting infringement of those patents. *See Elite Licensing, Inc., v. Thomas Plastics, Inc.*, 250 F.Supp.2d 372, 386

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[1] Defendants include Amersham plc and Amersham Biosciences, Inc. (collectively, "Amersham"), Molecular Probes, Inc. ("MPI"), PerkinElmer, Inc. and PerkinElmer Life Sciences, Inc. (collectively, "PerkinElmer"), Orchid Biosciences ("Orchid"), Affymetrix, Inc. ("Affymetrix") and Roche Diagnostics GmbH and Roche Molecular Systems, Inc. (collectively, "Roche") (with more than any one of them referred to as "Defendants").

[2] In addition to alleging non-infringement of certain of the asserted patents by some, but not all, of the accused products, curiously, Defendants also raised several non-patent defenses, including a contract-related payment defense and a defense to Enzo's Lanham Act claims. Because these defenses contradict the Court's Order, dated August 25, 2011 (D.I. 247), which granted Defendants' request to exclude non-patent related issues from the purview of this Renewed Motion, the Court should disregard those portions of Defendants' memorandum in their entirety.

(S.D.N.Y. 2003). Likewise, Defendants' motion ignores inconsistent claim construction rulings concerning the identical disputed claim elements which were adopted by Judge Arterton in the District of Connecticut, and subsequently affirmed by the Court of Appeals for the Federal Circuit. These facts alone, conspicuously missing from Defendants' moving memorandum, independently suffice to justify denial of Defendants' motion for summary judgment.

Moreover, as described in detail below, each of Defendants' accused products infringe one or more claims of the Enzo patents, either literally or under the doctrine of equivalents. Enzo submits herewith the declarations of Dr. Richard R. Sinden ("Sinden Decl.") and Dr. Archibald S. Perkins ("Perkins Decl.") which attach hundreds of claim charts detailing, on an element-by-element basis, why each of the accused products infringe Enzo's patent claims; and explaining why the relevant features of the accused products meet the claim limitations and/or are insubstantially different from them. (Sinden Decl. ¶¶ 51-85; Perkins Decl. ¶¶ 15-61)[3] Enzo also relies on admissions and other dispositive evidence in deposition/hearing testimony, declarations of fact and expert witnesses, prior summary judgment briefing and oral argument, and documents produced by Enzo and the Defendants. Defendants were fully aware of this evidence and expert analyses from the prior summary judgment proceedings, yet failed to address, let alone controvert, it in any meaningful respects.

While Enzo believes the evidence of record proves infringement, at the very least, Enzo's affirmative and uncontroverted evidence, as well as Defendants' numerous admissions against interest, raise genuine issues of material fact -- particularly when all doubts are resolved in favor of Enzo and their experts, as they must on summary judgment. *See Enzo Biochem Inc. v. Applera*

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[3] The Sinden and Perkins declarations are separately filed herewith. Unless otherwise noted, all other exhibits referenced herein are attached to the Declaration of Justin MacLean, Esq. in Support of Enzo's Opposition to Defendants' Renewed Joint Motion for Summary Judgment.

Corp., 599 F.3d 1325, 1338 (Fed. Cir. 2010). Accordingly, Defendants have failed to carry their burden of demonstrating an absence of any disputed issues of material fact, and their motion for partial[4] summary judgment should be denied.

BACKGROUND FACTS

I. Enzo's Pioneering Patented Technologies and Defendants' Need for Them

Plaintiff Enzo is an integrated life sciences and biotechnology company engaging in the research, development, manufacture, and sale of innovative products in the areas of biotechnology and molecular biology. Formed in 1976, Enzo developed and holds the rights to numerous "pioneering" technologies, including modified nucleotides, kits for making and using those nucleotides, and other labeling and detection technologies across research and diagnostic markets. In 1981, Enzo acquired the exclusive rights to develop and exploit certain modified nucleotides invented by Yale Professor David C. Ward and others ("the Ward patents" including the '824 and '767 patents-in-suit). As set forth in the declarations of Drs. Sinden and Perkins, Enzo's patented technologies were "pioneering" contributions to the industry that represented major advances in the ability to detect and quantify a polynucleotide sequence in a sample based upon hybridization, including by providing the fundamental structures of modified nucleotides that have proven enormously successful for many scientific research and commercial

[4] Defendants' Renewed Motion should be treated as one for "partial" summary judgment because Defendants have failed to move for summary judgment of non-infringement on numerous products accused of infringing Enzo's patents, and/or on "all" of the patents-in-suit as they incorrectly suggest in their motion (p. 1). For instance, Defendants' motion fails to address two of the eight patents-in-suit (U.S. Patent Nos. 5,082,830 and 4,943,523), does not contest that many of Defendants' products read on the claims of the patents-in-suit, and does not provide any sort of defense at all for certain accused products of MPI and Amersham. (*See* Exs. 1 and 2). To resolve any questions as to infringement by these products, Enzo submits the still-unopposed claim charts of Dr. Sinden's declaration showing how they fall within the scope of the asserted claims. (*See* Sinden Decl., Exs. 14 and 10 and ¶¶ 71-84, 51-62, respectively).

applications, such as *in situ* hybridization that enables detection of genetic disease as well as the sequencing of the human genome. (*See* Sinden Decl. ¶¶ 16, 40; Perkins Decl. ¶ 24).

Defendants Roche, PerkinElmer, Amersham and Affymetrix at various times (and through various predecessors) all develop, manufacture, and sell biotechnology products, including labeled nucleic acid kits and related technologies. In the early 1990's, each of these companies negotiated agreements ("Distributorship Agreements") with Enzo because they wanted access to Enzo's pioneering patents, proprietary technology and products. (Exs. 8-11).[5] Defendants MPI and Orchid were, at relevant times, appointed by PerkinElmer under its Agreement as authorized distributors of the accused products. REDACTED REDACTED REDACTED Defendant Amersham, which also independently entered into a Distributorship Agreement with Enzo (Ex. 10), REDACTED REDACTED

II. The Patented Inventions

A. The '824 and '767 Patents

The inventions of the '824 and '767 patents are directed to labeling of a nucleic acid sequence in a way that does not "substantially interfere" with hybridization of the complementary (or mating) nucleic acid sequences. (*See* Sinden Decl. ¶¶ 32, 57; Ex. 5, '824 patent, col. 6, ll. 42-54). Prior art labels and labeling methods predominantly used radioactivity, which suffered from safety, stability, and cost problems. (*Id.*, including at col. 1, ll. 20-50). The

[5] Specifically, Defendant PerkinElmer, through its predecessor in interest NEN Life Science Products, Inc., entered into a Distributorship Agreement, dated January 1, 1999 (Ex. 8); Defendant Roche, through its predecessor Corange International Limited, entered into a Distribution and Supply Agreement, dated April 25, 1994 (Ex. 9); Defendant Amersham entered into a Distributorship Agreement, dated February 21, 1995 (Ex. 10); and Defendant Affymetrix entered into a Distributorship Agreement, dated April 24, 1998 (Ex. 11).

invention overcame this problem through a pioneering discovery that one could attach a non-radioactive label ("A" per the claims) to a particular location (or site/position) on the nucleic acid base ("B" per the claims) via a specific type of linkage group that did not cause substantial interference under certain conditions. (*Id.*, including at col. 6, ll. 52-54). The '824 and '767 patents identify the specific positions on the base, i.e., the 5-position of a pyrimidine base or the 7-position of a 7-deazapurine base, where a label could be attached without causing substantial interference. (*Id.*). The claims of the '824 and '767 patents are generally directed to a "compound" that includes a base "B" that is covalently attached (represented by the dotted line) to a signaling moiety "A," either directly or through a "linkage group" that does "not interfer[e] substantially" with hybridization and detection. (*Id.*, claim 1; Ex. 6, '767 patent, claim 42).

B. The '373 Patent

The invention of the '373 patent is directed to the determination of whether targeted substances, described as "analytes," are present in biological or non-biological samples, such as "blood[,] urine, feces, saliva, pus, semen, serum, other tissue samples, fermentation broths, culture media, and the like." (Ex. 7, '373 patent, col. 5, l. 22-27). These target analytes to be detected can be a virus such as HIV, bacteria or other nucleic-acid containing etiological agents. (*Id.*, col. 1, ll. 27-40). Prior art techniques for detecting the presence of an analyte in a sample generally did not provide for quantitating (i.e., determining the amount of) the analyte in the sample. (*Id.*, col. 4, ll. 34-44). The invention describes a method of detecting and quantitating the particular nucleic acid sequence of the analyte in a sample through the use of a second nucleic acid sequence ("a probe") that is "complementary" to, or that will hybridize with, the "target" sequence of interest. (*Id.*, col. 5, ll. 15-21; Perkins Decl. ¶ 28). This is done is by affixing one of the complementary nucleic acid sequences to a solid support (e.g., glass) and then exposing it to a solution containing the other complementary nucleic acid sequence. (*Id.*,

including col. 5, ll. 37-60). The label attached to the complementary nucleic acid sequence in solution generates what the patent refers to as a "soluble signal" upon hybridization with the fixed sequence. (*Id.*, including col. 5, ll. 57-63). This quantifiable, soluble signal is preferably generated by fluorescent or colormetric labels that are detectable by spectrophotometric and/or colormetric assay techniques. (*Id.*, col. 7, ll. 46-47; and claim 3). Detection of this "soluble signal" (e.g., light, color change, etc.), enables the particular analyte of interest to be distinguished from unlabeled sequences and thereby the condition, etiological agent, gene disorder or the like to be diagnosed. (*Id.*)

III. The Parties' Distributorship Agreements "Dominate" the Patent Issues

As indicated above, each of the Defendants entered into Distribution Agreements with Enzo long before the instant litigation was filed to gain access to Enzo's proprietary technology and patents. (*See* Exs. 8-11). The Distributorship Agreements are highly relevant in several respects to Defendants' non-infringement and "authorization" defenses.

Each of the Distributorship Agreements identified representative products ("PRODUCTS") covered by the agreement which were listed in attachments to their respective agreements. (*See, e.g.*, Ex. 8 at Exs. B and C; Ex. 9 at Exs. A-K; Ex. 10 at Ex. B; Ex. 11 at Ex. B). REDACTED

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Importantly, each of the Distributorship Agreements list all eight (8) of the patents-in-suit, including the '824, '767 and '373 patents that are the subject of this motion. (*Id.* at Ex. A; Ex. 9, Roche Agreement, at Appx. A; Ex. 10 at Ex. A; Ex. 11 at Ex. A). In addition, many of the

Defendants marked their PRODUCTS with Enzo's patent numbers, acknowledging publicly their belief that such PRODUCTS infringe Enzo's patent claims. (*See, e.g.*, Ex. 41).[6]

In addition to entering into a Distributorship Agreement, Defendant PerkinElmer also entered into a Settlement Agreement with Enzo. (Ex. 12). REDACTED

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[6] Patent marking is where a product is "marked" with (or bears) one or more patent numbers on the product itself or its packaging. This is a requirement of the patent statute that is intended to notify third parties that a product is covered by the patent(s) and thereby that any unlicensed making, use, or sale by them or others would constitute infringement. *See* 35 U.S.C. § 287(a); *Wine Ry. Appliance Co. v. Enter. Ry. Equip. Co.*, 297 U.S. 387, 388, 397-98 (1936).

[7] PerkinElmer's product literature states that the accused Acyclo products are "covered by U.S. Patents 5,047,519 and 5,151,507". (*See* Ex. 16).

IV. The Accused Products

Enzo has asserted infringement of numerous products manufactured and sold by each of the Defendants. For a comprehensive list of accused products, see Exhibits 1-4.

V. Prior Related Proceedings

As this Court is aware, Judge Sprizzo issued a *Markman* ruling in July 2006 that construed most, but not all,[8] of the claim terms that Defendants argue in the present motion are not met by certain of their accused products. (D.I. 152) (Ex. 20). The Court also permitted Defendants to file multiple summary judgment motions on both patent (non-infringement and

[8] As addressed below in Argument Section II.A.5., the Court never construed the '824 patent to be limited to the meaning Defendants unilaterally ascribe to it (Renewed Motion at 21-22) because Defendants never asked for such an unduly narrowed construction during *Markman*.

validity) and non-patent (contract-related) issues. (D.I. 154). At oral argument, Defendants voluntarily withdrew their invalidity motions. (Ex. 78, Hearing Tr. 87:4-16, July 17, 2007). The Court did not rule on any of the remaining motions that had been filed. Following transfer of these actions, your Honor permitted Defendants, by order dated August 25, 2011 (D.I. 247), to re-file their joint summary judgment motion solely with respect to patent issues.

Importantly, after Judge Sprizzo issued his claim construction order, both Judge Arterton of the District of Connecticut and subsequently the Court of Appeals for the Federal Circuit adopted very different claim constructions of the '824 and '767 patents. *See Enzo Biochem, Inc. v. Applera Corp.* No. 04-929, 2006 WL 2927500 (D. Conn. Oct. 12, 2006) (attached as Ex. 19); *Enzo*, 599 F.3d 1325 (Fed. Cir. 2010) (affirming in part and reversing in part Judge Arterton's summary judgment rulings based on her claim construction).[9]

For convenience, below please find a comparison of certain of the claim constructions adopted by Judge Sprizzo and Judge Arterton:

Claim Limitation	**Judge Sprizzo's Construction**	**Judge Arterton's Construction**
"A comprises at least three carbon atoms and represents at least one component of a signalling moiety capable of producing a detectable signal" ('824 patent, claim 1; '767 patent, claim 42)	"Claim 1 of the '824 patent and claim 42 of the '767 patent require that 'A' be one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide." (Ex. 20, at 23)	"A comprises at least three carbon atoms and is one or more parts of a signalling moiety, which includes, in some instances, the whole signalling moiety." (Ex. 19, 2006 WL 2927500, at *4) "The Court finds that the plain language and structure of the '824 and '767 Patents indicate that these patents cover both direct

[9] As the Court may recall, the parties agreed to stay the present lawsuits based on the impact a decision by the Federal Circuit could have on the issues before this Court. Defendants cite to the Federal Circuit's decision in footnote 8 (p. 5) to inform the Court of the invalidation of the '928 patent, but neglect to mention how its adoption and application of Judge Arterton's claim construction of the '824 and '767 patents impact the present dispute over those terms.

Claim Limitation	Judge Sprizzo's Construction	Judge Arterton's Construction
		and indirect detection." (*Id.* at *3)
"soluble signal" ('373 patent, claim 1)	"Claims 1, 17, 18, and 25 of the '373 patent require, in their use of 'soluble signal,' the creation of a soluble, or uniformly dispersed, product which generates a detectable signal." (Ex. 20, at 24)	"[A] signal that does not precipitate and is thus detectable by spectrophotometric and/or colormetric assay techniques, such as colormetric, photometric and fluorescent signals." (Ex. 19, 2006 WL 2927500, at *14)

Although the Federal Circuit did not explicitly address issues of claim construction on the appeal of the Connecticut Action, in order for it to have ruled on issues of invalidity, it implicitly had to adopt Judge Arterton's claim construction positions relating to the '824 and '767 patents which were the subject of the appeal. *See Gechter v. Davidson*, 116 F.3d 1454, 1457 (Fed. Cir. 1997) ("Implicit in [the Federal Circuit's] review of [a lower court's] anticipation analysis is that the claim must first have been correctly construed to define the scope and meaning of each contested limitation.") Furthermore, the Federal Circuit's construction of a given patent claim must be given nationwide *stare decisis* effect, even as to non-parties to the initial litigation. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996); *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998); *Pass & Seymour, Inc. v. Hubbell Inc.*, 2011 WL 32433, at *2 (N.D.N.Y. Jan. 5, 2011).

Notably, Defendants' motion fails to identify the differences between the claim constructions adopted by Judge Sprizzo and the constructions applied by Judge Arterton and the Federal Circuit. The reason for their silence is readily apparent upon review of those intervening court decisions which as shown above held, *inter alia*, that "these patents cover both direct and indirect detection" (Ex. 19 at *3) and that the "A" moiety of the '824 and '767 patent claims may be "one or more parts of a signaling moiety, which includes, in some instances, the whole

signaling moiety" (*Id.* at *4) -- rulings that directly contradict Defendants' principal non-infringement arguments presented in their Renewed Motion (*See* Section A, pp. 12-16).

Although the Federal Circuit only dealt with the '824 and '767 patents and did not rule on the '373 patent, Judge Arterton did construe the "soluble signal" limitation of claim 1 that is disputed in this Renewed Motion and reached a somewhat different conclusion from Judge Sprizzo. Specifically, Judge Arterton held that the inventors wanted to distinguish their invention from previous methods utilizing so-called insoluble signals such as precipitates, but that they were less concerned with the actual solubility of the signal than the method of detection, including spectrophotometric techniques (*see, e.g.,* Ex. 7, dependent claim 13, "device capable of transmitting ***light*** there through for the detection of said ***soluble signal***"). Concluding that the inventors were their own lexicographers in defining the signal that they had in mind -- i.e., light/fluorescence (including color) -- as "soluble" (even though from a strictly technical standpoint light/fluorescence may not actually dissolve in solution), the Court ultimately ruled that the claimed "soluble signal" can include light because dependent claims 3, 15 and 19 called for the soluble signal to be a fluorescent (or colored) product -- in contrast to an enzyme/co-enzymatic product (claim 4) -- that can be detected with a spectrophotometer. (Ex 19 at *13-14). Critically, this construction also directly refutes Defendants' position in its Renewed Motion (pp. 32-33) that the claimed invention somehow excludes from its scope the use of fluorescent-labeled products.

Thus, Judge Sprizzo and Judge Arterton construed the identical language of the '824, '767 and '373 claims differently.[10] Moreover, the Federal Circuit's subsequent decision which,

[10] While we recognize that this Court has adopted Judge Sprizzo's constructions, Enzo continues to object to those constructions because they are inconsistent with the intrinsic record, and contradicted by the constructions imposed by Judge Arterton and subsequently adopted by the

by necessity, adopted and applied Judge Arterton's constructions of the '824 and '767 patents was not available to nor considered by Judge Sprizzo in the instant lawsuits.[11] In any event, as shown below, under either set of constructions, Defendants' accused products infringe.

ARGUMENT

I. The Relevant Legal Standards

A. Summary Judgment

Summary judgment is granted pursuant to Rule 56(c), FED.R.CIV.P., only when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). "[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the 'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue

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Federal Circuit. Enzo believes that the claims should be construed as Judge Arterton held and that it could save unnecessary time and expense on appeal if this Court would reconsider the constructions imposed by Judge Sprizzo in favor of the constructions adopted by the District of Connecticut and the Federal Circuit.

[11] Without question, a court may engage in a rolling claim construction, in which it revisits and clarifies or alters an interpretation of the claim terms including as its understanding of the technology evolves. *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002). Such authority to revisit claim construction extends to summary judgment, or beyond. *See, e.g., Tesco Corp. v. Weatherford Int'l, Inc.*, 750 F. Supp. 2d 780, 787-93 (S.D. Tex. 2010)(rendering altered and clarified claim constructions in deciding motions for summary judgment); *RemoteMDx, Inc. v. Satellite Tracking of People*, LLC, 2009 WL 1605292, at *1 (C.D. Cal. Apr. 29, 2009)(prior *Markman* order vacated after "carefully scrutiniz[ing] all submissions by the parties" and "concluding that a different construction is appropriate"); *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1315-16 (Fed. Cir. 2010)(upholding the district court's right to alter the meaning of a claim term at trial); *U.S. Philips Corp. v. Iwasaki Elec. Ltd*, No. 03 Civ. 0172, 2006 WL 2792693, at *8 (S.D.N.Y. Sept. 28, 2006)(confirming that "further claim construction was not foreclosed at anytime during the pretrial stage and that the court was not locked into a position merely because it had conducted a *Markman* hearing and had ruled.")

of material fact." *Celotex*, 477 U.S. at 323 (*quoting* FED. R. CIV. P. 56(c)). The Court must view the evidence in the light most favorable to the nonmoving party, according that party the benefit of all justifiable inferences. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). In resolving all doubts in the respondents' favor, including with respect to evidence such as expert declarations, a court must remain "[m]indful that respondents' version of any disputed issue of fact…is presumed correct." *Eastman Kodak Co. v. Image Tech Servs.*, 504 U.S. 451, 456 (1992); *Enzo*, 599 F.3d at 1338.

B. Infringement

A determination of patent infringement involves a two-step analysis: first, a court must construe the claims asserted to determine their meaning and scope; and second, the fact finder compares the claims to the features of the accused products to determine if all of the "limitations" of at least one claim are present, either literally or under the doctrine of equivalents. *See Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1375 (Fed. Cir. 2006); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999). Although claim construction is a matter of law, whether the accused product infringes the properly construed claims is a question of fact. *Abraxis Bioscience,* 467 F.3d at 1375.

Summary judgment of non-infringement can only be granted "if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." *Pitney Bowes*, 182 F.3d at 1304. And, because infringement is a fact issue, "a motion for summary judgment of infringement or noninfringement should be approached with a care proportioned to the likelihood of its being inappropriate." *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1573 (Fed. Cir. 1985).

1. Literal Infringement

After the claims have been construed, the fact-finder must determine whether the accused product "meets each claim limitation either literally or under the doctrine of equivalents." *See Catalina Mktg. Int'l, Inc. v. Coolsavings.Com, Inc.*, 289 F.3d 801, 812 (Fed. Cir. 2002). To prove literal infringement a patentee must show that the accused product contains each limitation of the asserted claim. *Id.* Summary judgment on literal non-infringement is only proper "when, construing the facts in a manner most favorable to the nonmovant, no reasonable jury could find that the accused system meets every limitation recited in the properly construed claims." *Id.*

2. Infringement Under the Doctrine of Equivalents

Even if an accused product does not literally infringe a patent claim, the accused product "may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused device either literally or equivalently." *Cyber Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1459 (Fed. Cir. 1998)(en banc); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). The Supreme Court has repeatedly emphasized and explained the importance and applicability of the doctrine of equivalents:

> "The language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty. If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying."

Festo Corp. v. Shoketsu Kinzoku Kabushiki Co., 535 U.S. 722, 731 (2002); *see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950).[12] Elements in the accused

[12] "[C]ourts have also recognized that to permit limitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing."

product are equivalent to a claim limitation when the differences between them are "insubstantial" to one of ordinary skill in the art. *Catalina*, 289 F.3d at 812.

Whether an element in the accused product is equivalent to a claim limitation under the doctrine of equivalents "requires an intensely factual inquiry." *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1381 (Fed. Cir. 2000). Summary judgment of non-infringement under the doctrine of equivalents is only proper "[w]here the evidence is such that no reasonable jury could determine two elements to be equivalent." *Warner-Jenkinson*, 520 U.S. at 39 n.8.

Several factors are used by courts to help inform a decision as to whether the differences between the accused product and patented invention are substantial or not, including the so-called "function/way/result" test and evidence of "known interchangeability" of the claimed limitation and the corresponding feature(s) of the accused product.

a. The Function/Way/Result Test

"Infringement may be found under the doctrine of equivalents when, absent estoppel, every limitation of the asserted claim, or its equivalent, is found in the accused subject matter, the latter differs from what is literally claimed only insubstantially, and it performs substantially the same function, in substantially the same way, to achieve substantially the same result." *Wright Med. Tech., Inc. v. Osetonics Corp.*, 122 F.3d 1440, 1444 (Fed. Cir. 1997) (citing *Warner-Jenkinson,* 520 U.S. at 39; *Graver Tank*, 339 U.S. at 608-09). The factual questions of whether an accused product and a claimed limitation perform a function that is substantially the same and/or do it in substantially the same way to achieve the same result, if disputed, are not appropriate for resolution on summary judgment. *See Overhead Door Co. v. Chamberlain Group, Inc.*, 194 F.3d 1261, 1270-71 (Fed. Cir. 2000).

b. Known Interchangeability

"The known interchangeability of substitutes for an element of a patent is one of the express objective factors … bearing upon whether the accused device is substantially the same as the patented invention." *Warner-Jenkinson,* 520 U.S. at 36; *see also Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) ("Interchangeability is a significant factor in determination of equivalency"). The test for known interchangeability, "[r]ather than focusing on physical ... compatibility, … looks to the knowledge of a skilled artisan to see whether that artisan would contemplate the interchange as a design choice." *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1383 (Fed. Cir. 2001). "Insofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element, the proper time for evaluating equivalency-and thus knowledge of interchangeability between elements-is at the time of infringement, not at the time the patent was issued." *Warner-Jenkinson*, 520 U.S. at 37. Known interchangeability is a question of fact that can preclude summary judgment, including where an accused mechanism was a known structure that "had, in fact, been substituted by [the patentee] for the structure disclosed in the…patent." *Caterpillar, Inc. v. Deere & Co.*, 224 F.3d 1374, 1380 (Fed. Cir. 2000).

c. Potential Limits on the Doctrine of Equivalents

i. Prosecution History Estoppel

Prosecution history estoppel can limit or prevent a patentee from relying on the doctrine of equivalents when the patentee relinquishes subject matter during the prosecution of the patent, either by: (i) a narrowing amendment for purposes of patentability, or (ii) clearly and unmistakably surrendering subject matter by arguments made to an examiner. *Aquatex Indus., Inc. v. Techniche Solutions,* 419 F.3d 1374, 1382 (Fed. Cir. 2005). The legal standard is an

objective one, and is measured from the vantage point of what a competitor would reasonably believe had been clearly disclaimed by the applicant to procure issuance of the patent. *Id.*

Arguments made to an examiner do not completely bar equivalents. *Festo*, 535 U.S. at 738 ("We have considered what equivalents were surrendered during the prosecution of the patent, rather than imposing a complete bar that resorts to the very literalism the equivalents rule is designed to overcome."). Rather, the focus of the inquiry, and scope of any disavowal, is based on the nature and overall context of the statements made by the patentee. *Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008). Where an applicant explains or merely recites what the claims cover and only disavows the prior art, estoppel only applies to the prior art and not to other equivalents. *Conoco v. Energy & Environmental Int'l,* 460 F.3d 1349, 1364 (Fed. Cir. 2006) (patentee's explanation of the meaning of "fatty acid wax" and how it differed from the prior art's metal stearates held to be a clear disavowal of metal stearates but not all fatty acid wax equivalents). Furthermore, when a patentee distinguishes prior art based on multiple features which collectively are argued to demonstrate differences from the prior art, separate estoppels are not created. *Read Corp. v. Portec,* 970 F.2d 816, 824 (Fed. Cir. 1992).

ii. The "All Elements" Rule, Vitiation and Dedication

The so-called "all elements" rule helps to guide a doctrine of equivalents analysis by ensuring that it is "assessed on a limitation-by-limitation basis, rather than from the perspective of the invention as a whole, and that no limitation be read completely out of the claim." *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1016-17 (Fed. Cir. 2006). However, it is important to keep in mind that "any analysis of infringement under the doctrine of equivalents *necessarily* deals with subject matter that is 'beyond,' 'ignored' by, and not included in the literal scope of a claim." *Id.* at 1018; *Ethicon Endo-Surgery, Inc. v. US Surgical Corp.*, 149 F.3d 1309, 1317 (Fed. Cir. 1998). As explained by the Federal Circuit:

> It is important to note that when we have held that the doctrine of equivalents cannot be applied to an accused device because it "vitiates" a claim limitation, it was not to hold that the doctrine is always foreclosed whenever a claim limitation does not literally read on an element of an accused device; such an interpretation of the "all elements" rule would swallow the doctrine of equivalents entirely.... A holding that the doctrine of equivalents cannot be applied to an accused device because it "vitiates" a claim limitation is nothing more than a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency.

Depuy Spine, Inc., 469 F.3d at 1018-19. Thus, "[t]here is no set formula for determining whether a finding of equivalence would vitiate a claim limitation, and thereby violate the all limitations rule. Rather, courts must consider the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless." *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1359 (Fed. Cir. 2005) (citations omitted).

In similar fashion, other disclaimer/dedication theories such as "specific exclusion" must be evaluated from the perspective of a person of skill in the art and the "[l]iteral failure to meet a claim limitation does not necessarily amount to 'specific exclusion.'" *Ethicon Endo-Surgery, Inc.*, 149 F.3d at 1317. Indeed, the specific exclusion principle only applies where a person of skill would understand a patentee to have "specifically identified, criticized, and disclaimed" the excluded configuration in the patent specification. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001); *see also Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1373 (Fed. Cir. 2000) (disclosed structure is equivalent even where distinguished from claimed structure, if statements in the patent are not "clear and uncontroverted" admissions of substantial differences but merely indicate preference that a structure operate in a certain way). Thus, the rearrangement of limitations in form or position does not obviate equivalents where no element is "missing" from the accused device, even if not

in one-to-one correspondence with the patent claim. *Corning Glass Works v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251, 1258-61 (Fed. Cir. 1989); *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 41-43 (1929).

Finally, "before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005).

II. The Doctrine Of Marking Estoppel Precludes Defendants From Denying Infringement Of The Enzo Patents

Under the doctrine of marking estoppel, "where a party knowingly and deliberately marks its product with a patent number for a period of years, thereby representing to the public that the product is covered by the patent, that party is estopped from later denying in an infringement suit that the product is covered by the patent." *Elite Licensing, Inc*, 250 F.Supp.2d at 385; *see also Gridiron Steel Co. v. Jones & Laughlin Steel Corp.*, 361 F.2d 791, 797 (6th Cir. 1966) (having marked the products with the patent number, the infringer is estopped from claiming that they do not embrace features of the marked patent). The act of "placing a patent number on a product will estop a manufacturer from denying that his product embodies the patent for purposes of liability for both patent infringement damages and patent license royalties." *Barnett v. Strom*, 265 F. Supp. 2d 946, 951 (N.D. Ill. 2003).

As Enzo pointed out over five years ago in the previous summary judgment proceedings, and Defendants fail to acknowledge or even attempt to rebut in their Renewed Motion,[13]

[13] In their reply brief in support of their original Joint Motion, Defendants cite to *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 113 F. App'x 930, 934 (Fed. Cir. 2004) for the proposition that "the Federal Circuit explicitly declined to endorse the theory" of marking estoppel. (D.I. 195, at 13.) However, the Federal Circuit merely "note[d] that the parties dispute the continued viability of the doctrine," but "f[ou]nd it unnecessary to address this issue" on the facts of the case before it. *Slip Track*, 113 F. App'x at 934 (emphasis added).

Defendants knowingly and deliberately marked specific products with Enzo's patent numbers, and for years benefited therefrom. (*See, e.g.*, Ex. 41). Defendants are precluded from now alleging non-infringement of the asserted patents and judgment of infringement should be granted in favor of Enzo as to all of the products so marked.[14] To allow Defendants to assert non-infringement after years of profiting from the manufacture, distribution, use and sale of products marked with Enzo's patents-in-suit is contradicted by operative case law and principles of equity. *Elite Licensing,* 250 F. Supp. 2d at 386.

At minimum, Defendants' marking of products as covered by (i.e., infringing) the patents-in-suit raises genuine issues of material fact as to infringement that warrant denial of their summary judgment motion.

III. Defendants Infringe The Ward '824 And '767 Patents

A. Defendants' Accused Products Infringe Claim 1 of the '824 Patent and Claim 42 of the '767 Patent

Enzo has asserted that Defendants Amersham, PerkinElmer, Orchid and Roche have infringed claim 1 of the '824 patent and that Defendants Amersham, PerkinElmer, MPI, Orchid and Roche have infringed claim 42 of the '767 patent, claim 42. For a complete listing of products infringing these claims, see Exhibits 2 and 3. Relying on specification sheets for the accused products, Enzo's expert, Dr. Richard R. Sinden, analyzed and found infringement on element by element basis of the '824 and '767 patents, and attached detailed charts showing this infringement. (Sinden Decl. ¶¶ 46-82, Exs. 10-13). Defendants have not and cannot dispute this evidence. Instead, Defendants point to two elements of the '767 and '824 patents as they were

[14] Plaintiffs recognize that the Court did not permit them to move for summary judgment on these and the other products/patents for which Defendants do not contest infringement (see fn. 4, *supra*), but respectfully submit that such a ruling is justified and would help to simplify and focus the issues for trial.